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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,037	10/27/2000	Peter Bennett Duff Whyte	U013032-6	8344
140	7590	05/17/2010	EXAMINER	
LADAS & PARRY LLP 26 WEST 61ST STREET NEW YORK, NY 10023			WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	
			NOTIFICATION DATE	DELIVERY MODE
			05/17/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/702,037	WHYTE, PETER BENNETT DUFF	
	<b>Examiner</b>	<b>Art Unit</b>	
	DEBBIE K. WARE	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 28-39, 46 and 75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-39, 46 and 75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 28-39, 46 and 75 are presented for reconsideration on the merits.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on May 26, 2009, was filed and received of record. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Response to Amendment***

The amendment filed November 5, 2009, and extension of time have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Foreign Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on April 30, 1998. It is noted that applicant has filed on June 5, 2006, a certified copy of the patent application as required by 35 U.S.C. 119(b).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-35 and 37-39 and 46 and 75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the colostrum fraction

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containing IGF-1, does not reasonably provide enablement for the presence of any and all growth factors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice and carry out the invention commensurate in scope with these claims. The specification does not provide enablement for any and all growth factors as presently claimed. One of skill in the art carrying out the process would not be able to predict that work performance will be improved with the colostrum fraction without the presence of IGF-1. Thus, the claims are not enabled for the breadth and scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-39, 46 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of “colostrum retentate fraction” in step (b) lacks antecedent basis in step (a). Also it is confusing what the “colostrum fraction” is or whether it is intended to be the retentate fraction of step (b). The metes and bounds of the claims can not be determined.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-39, 46 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by newly cited 282898, cited on a previously submitted PTO-1449 Form.

Claims are drawn to a colostrum fraction which can improve work performance once ingested.

The reference 282893 teaches preparing a colostrum fraction which can improve exercise. See pages 4-5, lines 1-25 and 10-25. Also see page 9, wherein ultrafiltration is carried out, see line 13. Note Table 1, the casein is contained in the fraction along with IGF-1, see page 18. Spray drying (page 9, line 25) is also carried out after ultrafiltration steps (page 9, line 19) to obtain the fraction. The heating temperature is less than 72 and 64 degrees centigrade. Centrifugation (e.g. flow-through) is disclosed.

The claims are identical to the cited disclosure of 282893 and are, therefore, considered to be anticipated by the teachings therein. All of the same steps are used to prepare the fraction and it contains IGF-1, and casein; thus it will have the ability of improving work performance since it is the same composition as claimed.

Throughput and residence time control during centrifugation are inherent to the teachings because the reference clearly discloses specified rates for centrifugation. Note page 14, lines 20-28. Also bacterial reduction will necessarily occur as a result of the disclosed centrifugation. Furthermore, since the heating occurs before centrifugation the temperature of 90 degrees centigrade will drop below 72 degrees centigrade, especially since temperatures below 64 degrees centigrade are disclosed to

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be desirable, note page 7, line 9. Improvement in bone deficiencies will promote the ability to do more exercise by an individual (e.g. human) ingesting the disclosed fraction.

Also the composition of the reference 282893 at page 20, line 1, is disclosed to contain 0.5 which is about 1 weight percent amount being administered. Hence about of 0.5 to 1 gram per kg per day ingested are within in the weight percent amount being ingested by the subjects of the cited disclosure.

The colostrum study is conducted over a period of at least four weeks, therefore, for the experimental subjects to ingest daily over a period of at least four weeks is disclosed, in accordance with the protocol described for the disclosed reference. In addition, to walking will be improved by improving the bone mass of an individual. Also improved bone mass will improve body mass and stature. Therefore, the claims are considered to be anticipated by the cited reference.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Deborah K. Ware/

Deborah K. Ware

Examiner, AU 1651